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09/665,077	09/19/2000	Michael Climo	7732-020-27 DIV	5645

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Steven B Kelber  
PIPER MARBURY RUDNICK & WOLFE LLP  
1200 19th Street N W  
Washington, DC 20036-2412

[REDACTED] EXAMINER

BORIN, MICHAEL L

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

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DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No. <b>09/665,077</b>	Applicant(s) <b>Climo et al.</b>
Examiner <b>Michael Borin</b>	Art Unit <b>1631</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Dec 10, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 3-11 and 18-28 is/are pending in the application.

4a) Of the above, claim(s) 3-11 and 23-28 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 18-22 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

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## DETAILED ACTION

### ***Status of Claims***

1. Response filed 12/10/02 is acknowledged. Applicant again addresses restriction requirement made prior to the first Office action on merits. The restriction requirement, which is still deemed to be proper, was made final in the Office action mailed 7/24/02.

Claims 18-22 remain under consideration.

Applicant's arguments have been fully considered and were deemed to be persuasive-in-part. Rejections not reiterated from previous Office actions are hereby withdrawn.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

2. Claims 18-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejections are maintained for the following reasons.

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A. The claims are still considered to be failing to particularly point out and distinctly define the metes and bounds of the subject matter. It remains unclear what is being treated, an infection resistant to lysostaphin (as stated in the preamble of claim 18) or infection resistant to cell-wall antibiotic, and/or to both lysostaphin and cell-wall antibiotic (as stated in the end of claim 18). While the preamble addresses infection resistant to lysostaphin only as the objective of the method, the end of claim requires whatever is being treated (which is not defined in the claim) to have strains resistant to both lysostaphin and cell-wall antibiotic. Such language makes claims ambiguous. The ambiguity is further augmented by conflicting statements in specification and applicant's response: specification states that "combination therapy is effective in suppression of strains resistant against either antibiotic, or combination thereof" (page 8, lines 5-7), while applicant's response states that "bacteria can be resistant to either a cell-wall antibiotic, or lysostaphin, but not both" (p. 4, last full paragraph).

B. Examiner maintains that there are two different ways of defining dosages used in the method, which make claims vague and indefinite. Applicants, in their response quote only the first way of defining the dosages (amounts of components sufficient to treat infection individually) but do not clarify how this amount is related to the second definition of dosages as being sufficient to suppress all of the strains that are

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resistant lysostaphin, and to cell-wall antibiotic, and to both lysostaphin and cell-wall antibiotic.

***Claim Rejections - 35 USC § 102 and 103.***

3. Rejection of claims 18-22 under 35 U.S.C. 102(b) as anticipated by Polak et al is maintained for the reasons of record.

Applicant argues, first, that Polak does not teach an *in vivo* method. Neither, however, is the instant method drawn to an *in vivo* method as claimed. As discussed in the first Office action (discussion of the restriction requirement, page 2), amendment of the claim to read on “method of treatment”, of something which is not specified, does not change scope of the claims to an *in vivo* method.

Next, applicant argues that the reference does not teach doses that are independently effective in therapeutically treating a staphylococcal infection in a mammal. As neither the dose, nor the mammal are identified in the instant claims, the claims read on treatment of any mammal. Consequently, the dose described in Polak is considered to be well within the range of known therapeutically effective concentrations of lysostaphin. See, for example, Oldham and Daley reference presented by applicant (J. Dairy Science, 1991, 74, page 4180), wherein lysostaphin was infused into mammary gland at dose as low as 0.016 mg/ml (1 mg in 60 ml - see

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Table 3; Note that the final effective concentration was at least three orders less, given that an average mammary gland weight is 6 Kg<sup>1</sup> and it would contain at least 1000 ml of milk).

4. Rejection of claims 18-22 under 35 U.S.C. 103(a) as obvious over Shaffner, taken together with Moreira and DeHart, is maintained for the reasons of record.

Applicants argue, again, that the referenced methods are *in vitro*. This argument is addressed in discussion of the preceding rejection.

Further, applicant argues that "applicants are first to discover that bacteria can be resistant to either a cell-wall antibiotic, but not both" and that Schaffner does not recognize this phenomena. Examiner is not clear how this argument is related to the method as instantly claimed because this "phenomena" is not reflected in the claims and the only claimed objective of the method is to enhance effectiveness of lysostaphin.

As to Moreira and DeHart references, the references are used to demonstrate that lysostaphin-resistant strains have increased sensitivity to penicillin or methicillin, i.e., to cell-wall antibiotics. Examiner maintains that an artisan will be motivated to

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<sup>1</sup>see, for example, US Pre-grant publication US 2002150981, which says that a bovine mammary gland is about 6 kg

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sup[press lysostaphin-resistant strains combining lysostaphin with penicillin or methicillin.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

February 21, 2003

mlb

